UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,502	02/06/2006	Katashi Nakashima	20060018A	7557

513 7590 01/22/2009

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
POCHAS, CHRISTOPHER MICHAEL	
ART UNIT	PAPER NUMBER
4121	
MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,502	NAKASHIMA ET AL.	
	Examiner	Art Unit	
	Christopher Pochas	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/31/2006, 12/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

1) Claims 1-16 are pending in the instant application.

2) Priority is claimed to Japanese patent application 2003-286103 and PCT/JP2004/011068. The Japanese patent application document was not considered because an English language copies was not provided.

Non-Final Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO01/034147 as evidenced by CA 2390933 A1 in view of U.S. Patent 4743249, and Staskin, the reference included in the applicant's IDS.

Claims 1-9, 11, and 13 Canadian patent application CA 2390933 A1 (hereafter 933,) is an English language equivalent of WO01/034147 which discloses in the abstract the use of 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide (hereafter KRP-197, the abbreviation used in the Canadian document) to treat urinary incontinence.

933 does not teach the transdermal delivery of this compound, however Staskin does teach the transdermal delivery of a drug to treat urinary incontinence, and

transdermal delicery is well known in the art of drug delivery and so this is taken to be an obvious variant of 933.

U.S. Patent 4,743,249 (hereafter 249,) discloses the use of a transdermal patch with a reservoir, an adhesive, a peelable liner, and a support as a delivery method for known drugs. The first paragraph of column 4 of 249 states, "In practicing this invention one can employ any systemically active drug which will be absorbed by the body surface to which the bandage is applied, consistent with their known dosages and uses. Of course, the amount of drug necessary to obtain the desired therapeutic effect will vary depending on the particular drug used. Suitable systemic drugs include, without limitation, anti-microbial agents such as penicillin, tetracycline, oxytetracycline..." Additionally, the published article written by Staskin (hereafter Staskin) discloses the transdermal delivery of a drug for treating overactive bladders.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of 933 (using KRP-197 to treat urinary incontinence) with the teachings of 249 (using transdermal patches as a drug delivery system) and Staskin to create a transdermal patch using KRP-197 to treat urinary incontinence, because it is well known in the art that transdermal delivery of a drug reduces liver damage and thereby reduces the chance of side effects..

2. Claims 10, 14, 15, and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over WO01/034147 as evidenced by CA 2390933 A1 as well as U.S.

Patent 4,743,249, and Staskin as applied to claims 1-9, 11, and 13 above, and further in view of U.S. Patent 6207184.

Claims 10, 14, 15, and 16 The use of oil, alcohols, etc. as emulsifiers, penetration enhancers, etc. is well known in the art of transdermal drug delivery.

The abstract of U.S. Patent 6207184 (hereafter 184,) discloses the use of fatty acids, fatty acid esters, and alcohols as penetration enhancers. Line 45 of column 3 of 184 reads, "Examples of skin penetration enhancers for enhancing skin penetration of active ingredient(s) include known skin penetration enhancers such as fatty acids, fatty acid esters, polyhydric alcohols, alcohols, surfactants, organic bases, organic acids, vitamins and lecithin." It is therefore prima facie obvious to combine the teachings of 184 with the above references to arrive at a transdermal drug delivery patch with the listed ingredients to enhance the penetration of the active ingredient, a technique which is well known in the art and commonly performed using the compounds of pending claims 10, 14, 15, and 16.

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO01/034147 as evidenced by CA 2390933 A1 as well as U.S. Patent 4,743,249, Staskin and U.S. Patent 4847250 as applied to claims 1-11 and 14-16 above, and further in view of U.S. Patent 4889793.

Claim 12 U.S. Patent 4889793 (hereafter 793) discloses a single adhesive layer type transdermal drug delivery patch with a support and a peelable liner. The paragraph which begins at line 31 of column 1 of 793 discusses the peelable liner, the paragraph of line 24 of column 11 of 793 dicloses the support, and the paragraph immediately following the last mentioned paragraph discloses the use of this invention as a trandermal drug delivery product.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of 793 with the above references to use a single adhesive layer type patch to deliver the compounds of the pending claims to treat urinary incontinence because this is the simplest, easiest to make, most common form of transdermal drug delivery patch known in the art.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-16** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent Application No. 2007/0092566 A1.

6. Although the conflicting claims are not identical, they are not patentably distinct from each other because the these references disclose the oral use of 4-(2-methyl-1-imidazolyl)-2, 2-diphenylbutylamide to treat urinary incontinence and it is shown above that a transdermal delivery patch is an obvious variant of drug delivery.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. **Claims 1-16** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-26 of U.S. Patent Application No. 2008/0107727 A1.

9. Although the conflicting claims are not identical, they are not patentably distinct from each other because these references disclose the oral use of 4-(2-methyl-1-imidazolyl)-2, 2-diphenylbutylamide to treat urinary incontinence and it is shown above that a transdermal delivery patch is an obvious variant of drug delivery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is (571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMP

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121